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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,413	04/15/2005	Rolf Neumann	PHDE020229US	8122

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EXAMINER	
SAIDI, AZADEH	
ART UNIT	**PAPER NUMBER**
3709	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/531,413	NEUMANN ET AL.	
	Examiner	Art Unit	
	Anita Saidi	3709	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *17-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 April 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 10/531314.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *15 April 2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-15 and 21, drawn to determining and presenting perfusion indices, using a reference perfusion index.

Group II, claim(s) 17-21, drawn to determining and presenting the quality of the measuring values.

2. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group I is a method and apparatus for determining and presenting the information concerning variations of the arterial oxygen saturation of the blood, using the first perfusion as the reference index and the subsequent indices are determined as relative deviations with respect to the reference value.

On the other hand, Group II is an method and apparatus for measuring and determining and presenting the quality of measured data.

There is no generic claim.

3. During a telephone conversation with Thomas Lundin on March 1st 2007 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-15 and 21. Affirmation of this election must be made by applicant in replying to this Office action. Claims 17-20 were withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Drawings

5. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the term "acoustic" on line 2 of claim 15 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended

replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

6. The disclosure is objected to because of the following informalities:

Page 1, line 4 refers to a method for presentation of the quality of the measuring values claimed in the cancelled claim 16.

Page 2, line 23, also refers to the cancelled claim 16.

The specification should be amended to delete claim 16.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 11 and 12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

On line 2 of claim 11, the term "tachometer display" has not been described in the specification, and it is not clear to the examiner why a "tachometer display" should be used as a graphic element.

On line 3 of claim 12, the term "spider diagram" has not been described in the specification, and it is not clear to the examiner why a "spider diagram" should be used.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

10. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Regarding claim 12, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

The phrase "notably as" on line 3 of claim 12 has been interpreted as "such as".

12. The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

It is unclear to the examiner if lines 3-6 of claim 1 are part of the limitation, or simply descriptive information.

Note: In view of the aforementioned, the claim limitation has been considered as best understood. An absence of a prior art rejection of any claim(s) should not be taken as an indication of allowable subject matter unless otherwise indicated.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

14. Claims 1-3, 5-8,13 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by US. Pat. No. 1,426,319 to Stephens (Stephens).

In ref to claim 1:

A method for the presentation of information concerning variations of the arterial filling with blood of organs of living beings on the user surface of a display unit, in which method the data required for the presentation is determined, using an algorithm (See page 1, lines 25-47), from measuring values produced by a non-invasive photometric measuring process for determining the arterial oxygen saturation of the blood, characterized in wherein a first perfusion index is defined as a reference value and the subsequent perfusion indices are determined as relative deviations with respect to the reference value (See page 1, lines 57-60 and page 4, lines 3-10), said relative deviations being presented as information concerning the variations of the perfusion on the user surface (See page 3, lines 85-91).

In ref to claim 2:

A method as claimed in claim 1, wherein the determination of the reference value takes place automatically at the beginning of the photometric measuring process (See page 4, lines 3-5).

In ref to claim 3:

A method as claimed in claim 1, wherein the instant of determination of the reference value can be chosen at will (See page 4, lines 3-5).

In ref to claim 5:

A method as claimed in claim 1, wherein the reference value as well as the subsequent perfusion indices are scaled by a factor (See page 1, lines 70-74).

In ref to claim 6:

A method as claimed in claim 5, wherein the factor is adjustable (See page 1, lines 70-74).

In ref to claim 7:

A method as claimed in one of the preceding claim 1, wherein the variation of the perfusion is presented in numerical form (See page 4, lines 79-81).

In ref to claim 8:

A method as claimed in claim 1, wherein analog graphic elements are used for the presentation (See page 3, lines 92-96).

In ref to claim 13:

A method as claimed in claim 1, wherein an upper alarm limit and a lower alarm limit are provided (Page 3, lines 36-44).

In ref to claim 15:

A method as claimed in claim 13, wherein an acoustic and/or optical alarm signal is triggered when the alarm limit is exceeded (Page 3, lines 36-44).

15. Claim 21 is rejected under 35 U.S.C. 102(e) as being anticipated by US. Pat. No. 6,658,276 to Kianl et al (Kianl).

In ref to claim 21:

A device, comprising a pulsoximeter (Col. 4, line 19) for determining arterial O2 saturation (Col. 1,lines 57-64) and for calculating perfusion index in order to determine information concerning variation of the perfusion, means for detection of interference signals (Col. 7, lines 10-11), and for estimating the quality of the measuring values acquired (Col. 7, lines 52-63) and information concerning a variation of the perfusion, and means for presenting the information (See 101,105 and 109 in Figs. 1A, 1B and 1C respectively).

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. Claims 4 and 9-10 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over US. Pat. No. 1,426,319 to Stephens (Stephens) in view of US. Pat. No. 6,658,276 to Kianl et al (Kianl).

In ref to claim 4:

Stephens teaches all the limitation of claim 1, see the claim rejection in ¶ 14 above.

However, Stephens does not teach:

The reference value is stored on a memory chip.

Kianl discloses:

A pulse oximetry user interface that is adapted to present data responsive to a physiological signal. The system of Kianl presents a method of measuring and displaying oxygen saturation and perfusion, in a trend graph (See Abstract). Therefor the pulse oximetry system of Kianl is analogues to the one of Stephens.

Kianl teaches:

The reference value is stored on a memory chip (Col. 11, lines 33-44) in order to show the collected data in a trend graph as it has been shown in Fig. 10.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have included a memory chip for storing the reference value of Kianl in the calibrated tissue and heart rate monitor of Stephens in order to show the collected data in a trend graph as it has been explicitly thought by Kianl.

In ref to claim 9 and 10:

Stephens teaches all the limitation of claim 1 and claim 8, see the claim rejection in ¶ 14 above.

However, Stephens does not teach:

Bar elements are used as the graphic elements and the relative variations of the perfusion are represented by different bar lengths.

Kianl is analogous to Stephens; see the aforementioned argument for rejection of claim 4.

Kianl teaches:

Bar elements are used as the graphic elements (See 610 in Fig.6 and Col. 7 lines 65-67) in order to indicate the quality of the

measured signal. Low signal quality may be due to various factors, such as improper sensor application, misalignment of the sensor's emitter and detector resulting in smaller signals, extreme changes in the patient's physiology and blood flow at the monitoring site. Therefor it is essential for the physician to see any changes in the signal quality/perfusion (See Col. 8, lines 5-16).

The relative variations of the perfusion are represented by different bar lengths (See Col. 8 lines 18-30) in order to indicate the quality of the measured signal. With small bar height corresponding to low signal quality and large bar height corresponding to high signal quality (See Col. 8, lines 26-30).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the display monitor of Kianl to include bar elements as graphic elements in the calibrated tissue and heart rate monitor of Stephens in order to show the change in the signal quality and tissue perfusion as explicitly thought by Kianl.

In ref to claim 14:

Stephens teaches all the limitation of claim 13, see the claim rejection in ¶ 14 above.

However, Stephens does not teach:

The alarm limit is adjustable.

Kianl is analogous to Stephens; see the aforementioned argument for rejection of claim 4.

Kianl teaches:

A pulse oximetry user interface with adjustable alarm limit settings (See Col. 12 lines 65-67) in order to give the physician the freedom of setting the alarms in a different range in order to monitor patients with special needs.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the pulse oximetry user interface of Kianl to include adjustable alarm limits in the calibrated tissue and heart rate monitor of Stephens in order to allow the physician the freedom of monitoring patients with special needs as implicitly thought by Kianl.

18. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over US. Pat. No. 1,426,319 to Stephens et al (Stephens) in view of US. Pat. No. 6,322,516 to Masuda et al (Masuda).

In ref to claim 11:

Stephens teaches all the limitation of claim 8, see claim rejection in ¶ 14 above.

However, Stephens does not teach:

A representation in conformity with a tachometer display is used as the graphic element

Masuda discloses:

A blood pressure monitor, an information-obtaining device that obtains physical information that changes with change of blood pressure of the subject. A display device, which displays a graph representing the pieces of information, obtained as tachometer in Fig. 11. The system
of Masuda has a control device, which controls the display device to display the graph representing the initial piece of information and each one of subsequent pieces of information iteratively obtained in order to compare the initial piece of information with the subsequent piece information (See Abstract).

This will help the physician to judge if the patient's current condition is not critical for initiating a blood pressure measurement (See Col. 2, lines 47-63). Since the area of each pulse of the peripheral pulse wave changes with the change of blood pressure,

the system of Masuda monitors the pulse rate intensity and oxygen saturation before initiating a blood pressure measurement (See Col. 1, lines 50-67 and Col. 7, lines 22-27).

Masuda teaches:

A representation in conformity with a dial display is used as the graphic element (See Fig. 11), which is corresponding to the bar graph (See Fig. 8) in order to represent the amount of change of each of the estimated blood pressure values in comparison the origin value (See Col. 19, lines 1-19).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have included a dial for displaying the deviation of the estimated blood pressure values in comparison to the origin value Masuda in the calibrated tissue and heart rate monitor of Stephens in order to show the deviation of the estimated blood pressure values in comparison to the origin as it has been explicitly thought by Masuda.

19. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over US. Pat. No. 1,426,319 to Stephens et al (Stephens) in view of US. Pat. No. 5,912,656 to Tham et al (Tham).

In ref to claim 12:

Stephens teaches all the limitation of claim 8, see claim rejection in ¶ 14 above.

However, Stephens does not teach:

> The display is formed as a multidimensional type in conjunction with other physiological variables, as a spider diagram.

Tham teaches:

> A device for producing a display from monitored data functions to read, store, encode and integrate monitored data of at least one data type from at least one monitoring device (See Fig. 8 and 10). The integrating indicia of at least one data type in the system of Tham produces a single superimposed and/or multidimensional image capable of portraying a present and historical data combination. The advantage of using a multidimensional image is that the related or unrelated datum is comprehensible at a glance by a user (See abstract).
> The aforementioned multidimensional display system of Tham is equivalent to a spider diagram.
>
> Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have included the multidimensional display of Tham in the calibrated

tissue and heart rate monitor of Stephens in order to see the related or unrelated datum at one glance as it has been explicitly thought by Tham.

Conclusion

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The US. Pat. No. 5,860,918 to Schradi et al has been cited because; it discloses a medial monitoring device for monitoring and displaying physiological parameters of a patient. The US. Pat. No. 4,869,253 to Craig, Jr. et al has been included because it discloses a method and apparatus for indicating perfusion and oxygen saturation trends in oximetry. The US. Pat. No. 4,689,615 to Del Rosso has been included because it discloses a visual display of the trend of a data source.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anita Saidi whose telephone number is 571-270-3001. The examiner can normally be reached on Monday-Thursday 6:30 am - 5:00 pm Est..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kenneth Bomberg can be reached on 571-272-4922. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AS 4/2/2007

THAO X. LE
PRIMARY PATENT EXAMINER